[JOINT COMMITTEE PRINT]

ISSUES ARISING IN THE DETERMINATION OF AN APPROPRIATE FUNDING SOURCE FOR THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

SCHEDULED FOR A HEARING

BEFORE THE

SUBCOMMITTEE ON SELECT REVENUE MEASURES

OF THE

COMMITTEE ON WAYS AND MEANS

ON MARCH 5, 1987

PREPARED BY THE STAFF

OF THE

JOINT COMMITTEE ON TAXATION

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INTRODUCTION

This pamphlet,[1] prepared by the staff of the Joint Committee on Taxation, provides an analysis of issues related to determining an appropriate funding source for the Federal compensation program established by the National Childhood Vaccine Injury Act of 1986 (Title III, P.L. 99-660) ("the Act"). The Subcommittee on Select Revenue Measures of the Committee on Ways and Means has scheduled a hearing on these issues on March 5, 1987.

The first part of the pamphlet is a summary of the new Federal vaccine injury compensation program and of issues arising in connection with enactment of a funding source for that program. The second part of the pamphlet provides a description of the Federal vaccine injury compensation program enacted by the Act and estimates of budget outlays for the program. The third part of the pamphlet contains a description of alternative funding sources for the new program, including both general revenues and dedicated excise taxes, and an analysis of the issues arising from enactment of various funding sources.

Finally, the pamphlet includes three appendices providing (A) an economic analysis of the effect of a Federal vaccine injury compensation program on manufacturers' behavior, (B) a summary of bills introduced in the 99th Congress to establish and fund vaccine injury compensation programs, and (C) an overview of vaccine injury compensation programs in certain other countries.

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[1] This pamphlet may be cited as follows: Joint Committee on Taxation, *Issues Arising in the Determination of an Appropriate Funding Source for the National Vaccine Injury Compensation Program* (JCS-4-87), March 4, 1987.

I. OVERVIEW

A. Summary of the National Vaccine Injury Compensation Program and Reasons for the Program

The National Vaccine Injury Compensation Program was enacted in 1986 [2] to provide a source of compensation for individuals who are injured or die as a result of administration of certain prescribed childhood vaccines (diptheria, pertussis, and tetanus (DPT), measels, mumps, and rubella (MMR), and certain polio vaccines).[3] The new compensation program is to be effective following enactment of a Federal funding source.

The new Federal compensation program is intended as an alternative source of compensation to civil tort actions against manufacturers of the prescribed vaccines. Unlike tort actions, however, the new system is a no-fault system.[4] Thus, no proof of fault on the part of the manufacturer is required—if an individual receives a vaccine and suffers any of the injuries for which compensation is authorized within a prescribed time period, compensation awards are to be made.

The new Federal compensation program substitutes a Federal insurance system for the existing State-law tort and private insurance system, as applied to vaccine manufacturers. The uncertainty of civil judgments against vaccine manufacturers, especially the amounts of such judgments, has led to significant price increases in recent years. For example, the price of the DPT vaccine has increased from $.10 per dose in 1982 to $3.01 per dose in 1986.[5] For 1987, the price is expected to be significantly higher due to an approximate $8.00 per dose surcharge imposed by manufacturers for a liability reserve.

In addition, the potential for unlimited damage awards has been cited as a factor discouraging manufacturers from producing childhood vaccines, thereby endangering the long-run vaccine supply. Enactment of the vaccine injury compensation program represented a determination that society as a whole, through the Federal Government, rather than vaccine recipients and manufacturers,

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[2] The National Childhood Vaccine Injury Act of 1986 (Title III, P.L. 99-660).

[3] The DPT, MMR, and polio vaccines are required to attend school in most States, although some States provide exemptions for medical, religious, and philosophic reasons. Of these, the highest rate of adverse reactions appears to be associated with the DPT vaccine, specifically the pertussis component, which contains whole (rather than attenuated), killed bacteria. For a discussion of the target diseases, vaccines, and risks associated with these vaccines, *see, Childhood Immunizations: A Report Prepared by the Subcommittee On Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, Committee Print 99-LL, 99th Cong., 2d Sess., September, 1986.

[4] The new Federal compensation program does not require that claimants show who manufactured the vaccine causing injury; rather the Federal Government is the respondent party in compensation actions.

[5] The 1986 price is the price on sales to the Federal Government; prices to private purchasers may be higher.

should assume responsibility for administration and funding of this type of compensation.

Proponents of the Federal compensation program believed that the combination of significantly higher prices and uncertain compensation for injuries could result in reduced compliance with the nation's childhood immunization program. For example, while the DPT, MMR, and polio vaccines are required to attend school in most cases, parents could delay immunizing their children until their entry into school, rather than pursuing medically recommended procedures for earlier vaccination.

Substitution of a Federal insurance system for the State-law tort (and private insurance) systems was believed likely to eliminate the perceived threat to compliance with the immunization program by lessening pressure for price increases by providing greater certainty of compensation for injuries (e.g., through specified amounts and lower standards of proof necessary for recovery), and by lowering administrative costs incurred in obtaining compensation, such as attorneys' fees.

Awards under the new compensation program generally are not paid on a lump-sum basis nor are the maximum amounts of such awards definitely set when made, except in the case of death for which lump sum awards of $250,000 are authorized, and pain and suffering awards, where lump-sum awards of up to $250,000 are authorized. Rather, the compensation is paid periodically over the life of the injured claimant in such amounts as are required to satisfy otherwise unreimbursable medical and custodial care costs incurred not more than one year after the date of each payment. After a successful claimant attains age 18, amounts equivalent to lost or reduced wages resulting from the vaccine-related injury also are payable.

B. Summary of Tort-Law Remedies for Vaccine Injuries

In addition to authorizing Federal compensation for vaccine injuries, the Act imposed new limits on permitted State-law tort recoveries in the case of vaccine injuries. Except as limited under the Act, tort-law recoveries remain the subject of State, rather than Federal law. The Act does not affect the tort liability under applicable State laws of any persons other than the manufacturers of the covered vaccines (e.g., physicians).

When the new compensation program is effective, all vaccine-related damage claims must first be determined by U.S. District Courts under the program. Following such a determination, each claimant must elect whether to accept as final settlement the amount (if any) awarded under the program, or to proceed in an appropriate State court with a civil tort action.

State-law tort remedies

Statutory and case law of the States varies; however, in most States, a recovery under tort law requires, at a minimum, a civil action against the manufacturer of the vaccine causing injury (or other responsible party) and a showing of fault on the part of the manufacturer in either the manufacture or marketing of the vaccine.

To recover damages against a manufacturer, a claimant must prove that his injury was caused by a defect that was present at the time it left the hands of the manufacturer. Such a defect may be in the manufacture or in the design of the product, or may consist of a failure to provide adequate warnings as to the risks associated with use of the product. Several State cases have held manufacturers to be at fault because of failure to provide direct warnings to users of the vaccines (as opposed to health care providers) of the dangers associated with a vaccine. In most States, it is not sufficient to prove merely that the product caused the injury for which recovery is sought.

The amount and structure of awards, like the standards for recovery, also are provided in State law. In general, except in the case of wrongful death actions for which maximum awards frequently are provided in State statutes, the amount of awards is within the discretion of the State courts (or the parties to the action in the case of negotiated settlements). Amounts awarded to plaintiffs may include economic damages (including medical and other costs, and lost or reduced earnings); damages for pain and suffering; and in some cases, punitive damages. Consistent with the termination of jurisdiction of a court following entry of a judgment, most tort awards historically have been for defined amounts, frequently to be paid as a lump sum.

Federal preemption of certain tort rules under the Act

As described above, the Act requires claimants to proceed under the National Vaccine Injury Compensation Program before filing a State-law claim against a vaccine manufacturer. If a State-law claim is filed, the Act preempts State tort law to a limited extent by imposing limits on recovery from vaccine manufacturers. Among these limits are a prohibition on compensation for injury or death associated with unavoidable side-effects; a presumption that vaccine manufacturers are not negligent in manufacturing or marketing vaccines if they comply, in all material respects, with Federal Food and Drug Administration requirements; and limits on punitive damage awards.

C. Summary of Alternative Funding Sources and Issues Arising in Connection With Such Funding Sources

Federal financing of a vaccine injury compensation program raises several issues, both as to revenue source and fiscal administration of the program and as to the economic and social consequences of such Federal Government action.

General revenues

The most direct recognition of a Federal obligation to the program would be to fund compensation awards out of general revenues. While appropriated general revenues would achieve the greatest sharing of the burden of costs of these awards through society, some suggest that such an action may not satisfy one of the objectives of the new no-fault compensation system—certainty of payment. These persons suggest that the appropriations process, being generally an annual process, may not provide this certainty,

especially in times of budgetary constraint.[6] There are, however, numerous Federal entitlement programs, notably, Aid for Families with Dependent Children (AFDC), that provide certain future payments by the Federal Government, notwithstanding required annual appropriations.

Dedicated excise taxes

Imposition of special, dedicated taxes deposited in trust funds has been chosen as the funding source for several Federal programs where Congress has determined that the cost burden is more appropriately borne by a limited group of persons having a more direct nexus to the purpose of the expenditures. Dedicated taxes included the employment taxes that fund the Social Security Trust Fund and the taxes financing the Unemployment Compensation Trust Fund; the excise tax on coal to finance the Black Lung Disability Trust Fund; and the excise taxes on motor fuels and other highway-related articles to finance the Highway Trust Fund.

Enactment of such dedicated taxes with stable tax rates may require greater precision in determining total program costs (over a period of years) than if general revenue funding is used. This need for precision in establishing program costs may be demonstrated through the history of the Black Lung Disability Trust Fund, which has experienced deficits for several years—a situation that in recent years has necessitated extensive borrowing from general revenues, some benefit reductions, and tax increases. This need for precision is lessened somewhat if, like the black lung disability program, the vaccine injury compensation program is given authority to borrow from general revenues. Alternatively, tax rates may be set high deliberately with an automatic reduction if revenues exceed program liabilities.

The smaller revenue base also increases the potential for economic distortion to the persons subject to a dedicated tax. If vaccine prices increase as a result of a tax on vaccines, the percentage of total vaccines purchased by the Federal Government and State and local governments could increase significantly as more vaccinations are administered through public health services, rather than by private physicians. These governments currently purchase approximately 50 percent of the vaccines sold in the United States. Imposing tax on sales to the Federal Government is substantively equivalent to appropriating monies from general revenues for payment of compensation awards and involves the same budgetary issues as funding from general revenues.

Government fiscal planning

If an excise tax/trust fund alternative is adopted, the Subcommittee must decide whether the tax should be sufficient to finance the trust fund on a fully funded basis or on a pay-as-you-go basis. Outlays from the trust fund will vary over time. In general, outlays will be greater in later years because the majority of payments received by individuals are made in years after the initial award is

[6] The compensation awards under the new program are not for set amounts.

made. It may take many years before the trust fund reaches this higher, "steady-state" level of annual outlays.

If an excise tax is set at a rate sufficient to finance only current outlays (a pay-as-you-go approach), then tax rates must be increased when higher annual outlays are experienced. As the trust fund matures, the rate of tax necessary to meet current outlays may result in significantly higher vaccine prices, reducing compliance with the State vaccination programs or placing further demands on public health agencies for the provision of vaccines. A fully funded method of financing would require higher initial tax rates, but may result in lower tax rates than for a pay-as-you-go system in later years. Further, a fully-funded approach may more accurately portray the true costs of the compensation program and the accrued liabilities of the fund.

Scheduled sunsets

An additional issue that arises in conjunction with enactment of dedicated taxes and trust funds is that of a scheduled sunset. In recent years, trust funds and excise taxes having a narrow revenue base and public works program trust funds generally—as opposed to broad-based entitlement programs like social security—frequently have been enacted with specific sunset dates to ensure periodic review of both expenditure assumptions and continued appropriateness of the taxes. In most cases, these trust funds require full funding of all future liabilities of the funds either on a current basis or before the scheduled sunset dates. Precise data is not available on long-run anticipated liabilities of the vaccine injury compensation program, and the amount of these future liabilities even to initial claimants is not definitely set at the time of their award. Thus, some persons might suggest that a sunset date is appropriate to permit review of the taxes and compensation program when more complete data is available.

In the case of the new Federal vaccine injury compensation program, claimants receiving awards in the first years following the program's effective date will continue to receive payments throughout their lives, long past any sunset dates normally enacted for trust funds. Failure to finance such a program on a fully funded basis before any scheduled sunset date is equivalent, however, to authorizing borrowing from general revenues in the later years. Adhering to the pattern of sunset dates adopted by Congress for many dedicated taxes and trust funds in recent years could require revision of the compensation program, as presently enacted, if a dedicated excise tax funding source is adopted, to permit accurate determination and funding of total future liabilities.

II. DESCRIPTION OF THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 AND ESTIMATED BUDGET OUTLAYS UNDER THE ACT

A. National Vaccine Injury Compensation Program

The National Childhood Vaccine Injury Act of 1986 [7] (the "Act") creates a National Vaccine Injury Compensation Program, under which a party suffering death or a prescribed injury as a result of certain specified vaccines [8] is required to file for compensation under a new Federal compensation program before bringing a civil action for damages against the vaccine manufacturer.[9] The new compensation program is administered by special masters in the U.S. District Courts.[10] Amounts compensable under the program include otherwise unreimbursed medical, rehabilitative, educational, and, where appropriate, residential and custodial expenses. Additionally, compensation is authorized for lost earnings and for up to $250,000 per claimant in damages for pain and suffering. In the event of death, compensation (other than unreimbursable expenses) of $250,000 is authorized. (Reasonable attorney's fees also may be recovered under the new compensation program.)

The program applies to vaccines received in the United States or its trust territories and, in certain cases, to vaccines received outside these areas (e.g., as a member of the U.S. armed forces stationed in another country.)

Following a determination under the new compensation program, a claimant may reject any award and bring a civil action for damages against the vaccine manufacturer. Recovery in any such an action is governed by general tort law principles, subject to specific modifications made by the Act. If the claimant accepts an award under the compensation program, the Federal Government is subrogated to any tort claims the claimant may have against the vaccine manufacturer.

The compensation program is to be effective once a funding mechanism is in place.

Eligibility for compensation

To recover under the new compensation program, a claimant is required to demonstrate, by a preponderance of the evidence, the following facts:

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[7] Title III of P.L. 99-660.

[8] *See*, Table 1, below.

[9] The new compensation program does not affect the ability of claimants to bring civil actions at any time against a party other than the vaccine manufacturer (e.g., a physician).

[10] A party may not seek compensation through the program for damages of $1,000 or less; however, a party may bring a civil action in such cases.

(1) The claimant received a vaccine covered under the compensation program, or else contracted polio (directly or indirectly) from another person receiving an oral polio vaccine.

(2) The claimant sustained, or significantly aggravated, any condition for which compensation is authorized under the program in conjunction with the relevant vaccine, or died as a result of the vaccine.

(3) The first symptom of the onset or significant aggravation of such condition (or death) occurred within the time period prescribed under the program.[11]

(4) The claimant has not previously collected damages (including a settlement) in a civil action for the vaccine injury or death.

Compensation may not be awarded, if there is a preponderance of the evidence that the claimant's condition or death results from factors unrelated to the vaccine in question.

Vaccines and injuries for which compensation authorized

The vaccines and injuries that are compensable under the Act are shown in Table 1.

TABLE 1.—VACCINE INJURIES FOR WHICH COMPENSATION IS AUTHORIZED UNDER P.L. 99-660

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigens	
A. Anaphylaxis or anaphylactic shock	24 hours.
B. Encephalopathy or encephalitis (i.e, brain damage)	3 days.
C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days.
D. Residual seizure disorder	3 days.

[11] Alternatively, the claimant may have sustained an injury (or death) that is not specified under the Act, or that did not occur within the indicated periods. In these cases, however, the claimant must demonstrate that the condition or death was caused by the vaccine in question.

TABLE 1.—VACCINE INJURIES FOR WHICH COMPENSATION IS AUTHORIZED UNDER P.L. 99-660—Continued

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, etc., arose within the time period prescribed	Not applicable.
II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid:	
A. Anaphylaxis or anaphylactic shock	24 hours.
B. Encephalopathy or encephalitis	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component); 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component); 3 days (for DT, Td, or tetanus toxoid).
D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, etc., arose within the time period prescribed	Not applicable.
III. Polio Vaccines (other than Inactivated Polio Vaccine):	
A. Paralytic polio:	
—in a non-immunodeficient recipient	30 days.
—in an immunodeficient recipient	6 months.
—in a vaccine-associated community case	Not applicable.

TABLE 1.—VACCINE INJURIES FOR WHICH COMPENSATION IS AUTHORIZED UNDER P.L. 99-660—Continued

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, etc., arose within the time period prescribed	Not applicable.
IV. Inactivated Polio Vaccine:	
A. Anaphylaxis or anaphylactic shock	24 hours.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, etc., arose within the time period prescribed	Not applicable.

The Department of Health and Human Services (HHS), in consultation with a new Advisory Commission on Childhood Vaccines, has authority to modify on a prospective basis the vaccine injuries for which compensation is authorized, or to change the time periods provided in the Act during which an injury or death must occur. The addition of new vaccines to the table, or the deletion of vaccines presently included, may be accomplished only by legislation.

Compensable amounts

In general

Under the Act, compensation for a vaccine injury or death includes the following items:

(1) Unreimbursable expenses in excess of $1,000, including reasonable projected and unreimbursable expenses,[12] incurred (or to be incurred) by the claimant for—

(a) medical or other remedial care, and

(b) rehabilitation (including special education and job placement), custodial care,[13] and behavioral therapy.

[12] Compensation is provided for expenses incurred both before or after the date of a compensation award. Compensation for residential and custodial care is to be sufficient to enable the compensated person to continue living at home.

[13] This may include, for example, the cost of institutionalization of a seriously injured claimant.

(2) Actual and anticipated loss of earnings.
(3) Actual and projected pain and suffering and emotional distress from the vaccine injury, up to $250,000.

Payments for projected expenses are to be made on a periodic, rather than a lump-sum, basis, with no payment being made for a period in excess of one year. Payments for pain and suffering, emotional distress, and previously incurred expenses may be made in a lump sum, as may payments for death.

No payments are authorized under the program for punitive damages.

Death benefits

In the event of a vaccine-related death, an award of $250,000 is authorized to be made to the estate of the deceased.[14]

Attorney's fees

In addition to the items described above, a claimant under the compensation program is to be awarded reasonable attorney's fees and other costs incurred in the proceeding. These may be awarded even if no other compensation is awarded, provided that the court finds that the claim was filed in good faith and that a reasonable basis for the claim existed.

Limitation to unreimbursable expenses

No compensation may be paid for any item or service under the program, to the extent that payment has been (or may reasonably be expected to be) made with respect to such item or service under a private insurance policy; a State compensation program; a Federal or State health benefits program; or a prepaid health plan. The Act further prohibits any health insurance policy or program from making payment of benefits under the policy secondary to the payment of compensation under the program.

Compensation for pre-effective date injuries

Under the Act, compensation with respect to an injury or death resulting from the administration of a vaccine before the effective date of the program is available for unreimbursable medical, rehabilitation, and other expenses incurred after the date of the judgment, and for death. (No awards for lost earnings, or for pain and suffering, are allowed.) For vaccines administered before the effective date of the program, a petition must be filed within 24 months after the effective date. Awards for such pre-effective date injuries are limited to 3,500 claimants.

Subsequent adjustment of awards

If the amount awarded for unreimbursable medical, rehabilitation, and other expenses incurred after the date of the judgment proves insufficient to meet such expenses, the claimant may petition the court (a) to increase the amount of the award or (b) to amend the periodic payment schedule for the award, or both. The

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[14] This amount, and the $250,000 maximum award for pain and suffering, are to be indexed for inflation as measured by the medical component of the Consumer Price Index, on an annual basis.

Federal Government also may petition for revision of an award, if an audit discloses the improper use of compensation or that an item of compensation is no longer required.

Subrogation to civil claims

Upon payment of compensation to any claimant, the Federal Government is subrogated to all rights of the claimant with respect to the vaccine-related injury or death. However, the Federal Government may not recover an amount in excess of the compensation paid to the claimant.

B. Authority to Bring Civil Tort Actions

If a person (or the Federal Government pursuant to a subrogated claim) brings a civil action for damages against a vaccine manufacturer, that action will generally be governed by State law. However, the Act modifies certain aspects of State law for purposes of such actions. First, no vaccine manufacturer may be held liable for compensatory or punitive damages arising from an injury or death associated with the administration of a vaccine after the effective date of the new compensation program, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings. For purposes of this rule, a vaccine is presumed to be accompanied by proper directions and warnings if the manufacturer shows that it complied in all material respects with applicable requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act, unless the claimant establishes (1) fraud or intentional wrongdoing, or (2) by clear and convincing evidence,[15] that the manufacturer failed to exercise due care notwithstanding its compliance with those Acts.

Second, no vaccine manufacturer may be held liable for damages resulting from an injury or death associated with the administration of a vaccine after the effective date solely because of the manufacturer's failure to provide direct warnings to the injured party (or his legal representative) of the potential dangers resulting from the administration of the vaccine. (Under this rule, warnings to the person administering the vaccine would be considered sufficient.)

Third, the Act specifies that actions against vaccine manufacturers are to be tried in three stages: (1) whether the manufacturer is liable is to be determined, (2) the amount of damages (other than punitive damages) is to be determined, and (3) if sought by the plaintiff, punitive damages (if any) are to be assessed against the manufacturer. If the manufacturer shows that it complied, in all material respects, with applicable requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, it may not, in any case, be held liable for punitive damages, absent a showing of fraud or intentional wrongdoing.

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[15] This is a stronger standard than the preponderance of the evidence standard generally applied in civil cases.

Statute of limitations

State statutes of limitations apply to civil actions against vaccine manufacturers. The Act provides that these limitation periods are to be tolled beginning on the date a petition is filed under the vaccine injury compensation program, and ending on the date a final judgment is entered on the petition.

Information reporting provisions

As part of the vaccine compensation program, the Act imposes information reporting and recordkeeping requirements on vaccine manufacturers and on persons administering vaccines.

C. Estimates of Budget Outlays for the Vaccine Injury Compensation Program

When the 99th Congress enacted the National Vaccine Injury Compensation Program, both the Congressional Budget Office (CBO) and the Committee on Energy and Commerce estimated the budget outlays that would occur under the compensation program, during fiscal years 1987 through 1991. These outlay estimates are presented below *for informational purposes only.* Subject to the considerations discussed below, this information may be helpful in establishing the order of magnitude of required appropriations should general revenues be chosen as the appropriate funding source for the compensation program. Similarly, should a dedicated excise tax be imposed as the funding source for the program, projected rates of excise taxes may be derived, based upon the estimated total number of vaccinations occurring annually and certain other factors, described below.

In evaluating the available data on program costs and an appropriate funding source for the program, several factors require careful consideration. First, the CBO and Energy and Commerce Committee outlay projections do not reflect the total accrued liabilities arising during the period 1987–1991, because most payments for which commitments are made during the initial years of the program will be disbursed periodically throughout the lives of the claimants, and may increase or decrease after an initial award is made, contingent on future circumstances. The estimated outlay figures represent only projected disbursements during this period—total accrued liabilities are significantly higher than those stated. Similarly, if accrued liabilities were fully funded by new, dedicated excise taxes, the tax rates might have to be significantly higher than those shown for funding on a pay-as-you-go basis.

Estimated outlays are very sensitive to assumed rates of incidence of adverse reactions and the severity of these reactions. Because there are no comprehensive Federal reporting requirements for vaccine injuries at the present time, these estimates should be used with caution. (A comprehensive reporting requirement is provided under the Act.) Additionally, the number of claims that would be made under a Federal no-fault compensation system such as that provided in the Act may be significantly higher than historical data based on the State-law tort system would indicate.

Congressional Budget Office 1986 projections

Table 2 presents CBO's projections of actual budget outlays (as opposed to total accrued liabilities) during the period 1987–1991. Outlays are higher for the first three years of the five years shown because, during this period, compensation is awarded for costs arising from a large number of injuries sustained before enactment of the compensation program in addition to compensation for current injuries.

TABLE 2.—CBO ESTIMATED OUTLAYS, FISCAL YEARS 1987–1991

[Millions of dollars]

1987	1988	1989	1990	1991	1987–91
72	156	114	44	46	332

Source: Congressional Budget Office, 1986.

If an excise tax on vaccines were used to finance these outlays, tax rates could be set on each type of vaccine (e.g., DPT, DT, MMR, and polio) proportional to the compensation expected to be awarded from the use of each. Information necessary to set rates in this manner includes (1) the relative risks of injury and the costs of different adverse reactions, determined across the different types of vaccines, and (2) the doses of each vaccine sold. The Centers for Disease Control currently collects limited information on the frequency of different adverse reactions. (The quality of this information should improve under the Act.) Given the voluntary nature of this reporting, however, available data on the different rates of incidence across vaccines may be inaccurate. Similarly, given the greater difficulty of receiving compensation under the tort system (as compared to the new no-fault compensation system), and the absence of an established reporting system for costs of injuries, accurate determination of tax rates reflecting costs of injuries may be difficult. A further complication is that even if accurate determinations of costs and incidence rates were available for any given year, the relative infrequency of adverse reactions may cause projections for future years to be statistically imprecise, as some variation would normally be expected to occur.

An alternative to setting tax rates in a risk-related manner would be to set tax rates equally across different vaccines. This method would be disadvantageous if it caused a reduction in compliance with less risky vaccines.

Committee on Energy and Commerce 1986 projections

Table 3 presents the 1986 projections by the Committee on Energy and Commerce of actual budget outlays (as opposed to total accrued liabilities) during the period 1987–1991. These projections assume lower attorneys' fees and lower incidence rates than are assumed in the CBO projections. Outlays are higher for the first three years of the five years shown due to the payment of compensation awards to claimants with pre-effective date injuries. If an excise tax on vaccines were chosen to finance these outlays, the

rate of tax could be determined in a risk-related or other manner as described above.

TABLE 3.—COMMITTEE ON ENERGY AND COMMERCE PROJECTED OUTLAYS, FISCAL YEARS 1987–1991 [1]

[Millions of dollars]

1987	1988	1989	1990	1991	1987–91
25	56	38	16	18	153

[1] These estimated outlays are based on H.R. 5546, as reported by the Committee on Energy and Commerce. That bill included an 8-year limit on retroactive eligibility for compensation awards. The Act does not include this limit, but limits retroactive eligibility to 3,500 claims, determined on a first-come, first-serve basis.

Source: Committee on Energy and Commerce, 1986.

III. DESCRIPTION OF ALTERNATIVE FUNDING SOURCES FOR THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM AND ISSUES ARISING IN CONNECTION WITH SUCH FUNDING SOURCES

Two of the alternatives for financing the National Vaccine Injury Compensation Program are general revenue appropriations and a special dedicated excise tax and trust fund. Parts A and B below discuss these alternatives. Part C examines various issues arising in connection with the alternative funding sources.

A. General Revenues

One possible way to finance the vaccine injury compensation program is by general revenue appropriations. An argument in favor of this approach is that vaccines serve a general public good, by inhibiting the spread of infectious diseases; compensation for vaccine-related injuries may be seen as a method of achieving this general purpose. Most Federal spending programs, including numerous health programs, are financed with general revenues. Compensation programs in several foreign countries are financed from general public funds, as described in Appendix C. Some of these countries compensate for vaccine injuries as part of more general health coverage plans.

B. Dedicated Excise Tax and Trust Fund

As an alternative to funding the new compensation program from general revenues, the Subcommittee may wish to consider creating a trust fund for this purpose, to be funded (in whole or in part) by a specially dedicated excise tax. Trust funds have been established to finance various Federal expenditure programs.

A vaccine injury compensation trust fund could be financed by an excise tax on the specific vaccines to which adverse reactions have been identified.[16] The taxes could be set for each vaccine in a manner to approximate the anticipated liabilities arising from the use of each type of vaccine. This approach would provide the strongest link between revenue sources and expenditure purposes. A similar approach is taken with the Black Lung Disability Trust Fund, which is funded by an excise tax on coal. A possible weakness of this approach is the incompleteness of information on the rates of adverse reactions for each vaccine.[17] Information reporting of adverse reactions, as provided by the Act, may allow more accu-

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[16] This approach was taken by H.R. 5546, the precursor to Title III of P.L. 99-660, as introduced in the 99th Congress. *See* Appendix B.

[17] The Centers for Disease Control currently collects voluntary reports of adverse reactions of vaccines administered primarily by public health agencies, but there is no mandatory Federal reporting of vaccine injuries.

rate determination of the different rates of taxation for each type of vaccine in the future.

An important feature of the vaccine market is that approximately one-half of all vaccines is purchased directly or indirectly with Federal and State government funds.[18] Even if an excise tax on vaccines is the source of funds for the compensation program, a significant portion of the total excise tax collected will be paid by the Federal Government using general revenues. Further, an excise tax may increase the private price of vaccines, relative to the price if general revenues are used to fund the program. Given the free provision of vaccines by public health agencies, the higher private price could create an even stronger incentive among individuals to receive all vaccinations from these agencies and may require an additional Federal Government contribution to the cost of the immunization program.

C. Issues for Consideration in Evaluating Alternative Funding Sources

The alternative financing sources have different implications on several issues that may affect the degree to which the compensation program achieves its objectives.

Price of vaccines

The prices of vaccines, inclusive of any excise tax, are likely to be higher if excise taxes on vaccines are used to finance a trust fund than if general revenues are used. The excise tax on the vaccine would be essentially an insurance premium to cover compensation for potential vaccine-related injuries, paid for by consumers and manufacturers. If, alternatively, general revenues are used to finance the trust fund, this insurance premium would be paid by society as a whole through the Federal Government.

Thus, the choice between an excise tax on vaccines and the use of general revenues to fund the compensation program depends, in part, on the degree to which the Federal Government should subsidize the cost of this insurance. As discussed in Appendix A, it generally is proper to include in the total private cost of a product the cost of injuries from the use of a product. Otherwise, the product will tend to be overused. Because the benefits of vaccines accrue to other individuals in addition to the vaccine-recipient (by reducing the likelihood of infection in non-immunized individuals), however, it may be proper in the case of childhood vaccines to reduce the private cost of vaccines. This can be accomplished by a Federal Government subsidy on the direct purchase price of vaccines or, alternatively, by subsidizing the cost of sustaining vaccine-related injuries.

Another concern is whether the price of vaccines will be lower after the implementation of the compensation program than under prior law. Here two prices to the consumer are important to consid-

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[18] Federal programs include grants to States for immunization programs, health block grants, the Indian Health Service, Medicaid, and medical care for military dependent children. State health agencies may additionally provide State funds. *See*, Institute of Medicine: Division of Health Promotion and Disease Prevention, *Vaccine Supply and Innovation*, (1985), p. 58, for data on public sector purchases as a percentage of all purchases for 1982.

er. One price is the direct price, including any tax, paid for the use of vaccines. A second price is the "price" paid by those who sustain injuries as the result of being vaccinated. This "price" depends on the likelihood and severity of a potential injury to the consumer, less compensation received for the injury. While a generous compensation system funded by an excise tax may increase the direct price paid by consumers, the "price" of injury is reduced. The effect of the compensation program on increasing compliance with State immunization programs depends on the effect of the program on both the direct price and the "price" of injury.

The total price of vaccines—consisting of the direct price and the "price" of injury—is unlikely to decline unless (1) the Federal compensation program is more efficient at providing insurance than the private sector and (2) the sales price of vaccines, before inclusion of any tax, is reduced by an amount approximating the compensation formerly paid by manufacturers and now provided by the compensation program (e.g., the insurance reserve surcharge charged to purchasers of the DPT vaccine). In practice, this latter price reduction might not occur immediately, but only as the reduced liabilities are recognized by manufacturers. At least one major vaccine manufacturer has notified its purchasers that there would be no immediate price reduction in its vaccine prices as a result of the new Federal compensation program. The amount of the eventual price reduction relative to the reduction of manufacturers' liabilities would depend in part on the competitive nature of the vaccine industry. With competitive markets, vaccine prices ultimately would be expected to decline by the full reduction in manufacturers' liabilities if the lower price did not increase the demand for vaccines. If the lower price increased the demand for vaccines, then the eventual price may decline by a smaller amount.

As stated earlier, the vaccine industry is composed of a small number of manufacturers. A small number of manufacturers does not imply that an industry is noncompetitive. Even an industry composed of a single firm may act competitively if other firms are free to enter the industry. If the vaccine industry or the market for a particular vaccine is not perfectly competitive, however, but either monopolistic or oligopolistic, a reduction of manufacturers' liabilities can reduce vaccine prices by either more or less than in competitive markets. The reduction in liabilities can also change the competitive nature of the industry, for example, by making entry into the industry more attractive to other firms.

Government fiscal planning

One issue the Subcommittee must address if an excise tax/trust fund alternative is adopted is whether the tax should be sufficient to finance the trust fund on a pay-as-you-go basis, a fully funded basis, or a mixture of these two approaches. Outlays from the trust fund will vary over time for several reasons. First, in the initial years of the program, a greater number of individuals may qualify for compensation than will qualify in later years, as awards are authorized to be made to up to 3,500 individuals with injuries incurred before the present-law program was established. Second, the majority of payments received by individuals are made in years after the initial award is made. For example, payments to individ-

uals for lost earnings are made only after an individual attains the age of 18. It may take many years before the trust fund reaches this higher, "steady-state" level of annual outlays.

If an excise tax is set at a rate sufficient to finance only current outlays (a pay-as-you-go approach), then tax rates must be increased when higher annual outlays are experienced. As the trust fund matures, the rate of tax necessary to meet current outlays may result in significantly higher vaccine prices, reducing compliance with the State vaccination programs or placing further demands on public health agencies for the provision of vaccines. A fully funded method of financing would require higher initial tax rates, but may result in lower tax rates than for a pay-as-you-go system in later years. Further, a fully-funded approach may more accurately portray the true costs of the compensation program and the future liabilities of the fund.

The fully funded and pay-as-you-go approaches are not exclusive. The Subcommittee could choose a tax reflecting a mixture of these approaches. Higher tax rates in the initial years could be used to develop a partial reserve, requiring less significant increases in the tax rate in later years. This pattern is illustrated by the present-law social security taxes, which are set in such a manner that the trust fund currently is accumulating reserves, which combined with lower estimated future tax revenues (due to a shrinking work force relative to the number of retired), are estimated to be sufficient to defray forseeable benefit outlays.

An estimate of the present value of the liabilities arising in the first five years of the operation of the compensation program has been prepared by a private firm.[19] These estimates are useful for considering the outlays that would be necessary to fully fund accrued liabilities of the compensation program. Equivalently, these are the outlays that the firm estimated would be necessary in order to purchase annuities to cover all anticipated future payments arising from compensation awards made initially in these years.

Table 4 presents these estimated outlays for a fully funded compensation program. For simplicity, it is assumed that awards for all injuries incurred before the effective date of the compensation program are paid by the program in the first year of operation. Outlays in later years reflect commitments for injuries sustained currently. Outlays are assumed to increase at the rate of inflation after the second year.

While the assumptions made in these estimated outlays differ in several important respects from those made by CBO and the Energy and Commerce Committee (Tables 2 and 3), the primary differences in the estimated outlays, especially in the later years, occur as a result of the differences between fully funding the compensation program and funding it on a pay-as-you-go basis. These outlays are significantly higher than required for pay-as-you-go financing in the first five years.

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[19] The assumptions on the incidence and severity of adverse reactions and other factors affecting the cost of the compensation program are independent of those used by CBO and the Energy and Commerce Committee in their earlier projections. These assumptions have not been reviewed by either of the above or the Joint Committee on Taxation.

TABLE 4.—ESTIMATED OUTLAYS TO FULLY FUND TRUST FUND, FIRST 5 YEARS

[Millions of dollars]

Year 1	Year 2	Year 3	Year 4	Year 5
196	110	114	119	124

Source: Putnam, Hayes & Bartlett, *National Vaccine Program Cost Estimates*, February 25, 1987.

Table 5 presents the estimated excise tax rates necessary to fund the compensation program, given outlays assumed in Table 4. The first year tax rate is higher than the rate in later years due to the private firm's assumption that compensation awards for all pre-effective date injuries are funded in this year. Even after the first year, however, the tax rate on DPT vaccine, from $3.77 to $4.28 per dose, exceeds the total 1986 per-dose price for DPT vaccine purchased by the Federal Government. The tax rates for the years shown are higher than under a pay-as-you-go system.

TABLE 5.—ESTIMATED TAX RATES NECESSARY TO FUND VACCINE COMPENSATION PROGRAM ON A FULLY FUNDED BASIS, YEARS 1–5

[Dollars per dose]

Vaccine	Year 1	Year 2	Year 3	Year 4	Year 5
DPT	$7.11	3.77	3.93	4.10	4.28
DT	.09	.05	.05	.05	.06
MMR	6.92	3.68	3.84	4.00	4.18
Polio	.46	.25	.26	.27	.28

Source: Putnam, Hayes & Bartlett, *supra.*, Years 1 and 2. Future year rates projected to increase at estimated rates of inflation.

Sunset dates

In recent years, several dedicated taxes and trust funds adopted by Congress have included sunset dates to ensure periodic review of both the expenditure programs and the revenue sources. Proponents of sunset dates might suggest inclusion of a scheduled sunset for any dedicated taxes adopted to fund the vaccine compensation program. While sunset dates typically have been adopted with trust funds for public works programs (e.g., the Highway Trust Fund) rather than for entitlement programs (e.g., the Black Lung Disability Trust Fund) to which the vaccine program is more closely analogous, some might suggest that paucity of data on the extent of vaccine injuries and potential compensation awards make a sunset date appropriate for any funding source chosen for the program. (The Act provides new information reporting requirements so that better data may exist at a later date.)

The decision on whether to provide a sunset date for any funding source the Subcommittee might adopt could affect decisions on the structure of that funding source. For example, setting tax rates to fully fund anticipated liabilities before the sunset date would protect future benefits of all claimants under the compensation program, while permitting an objective review of the program at a specified date. A pay-as-you-go approach, on the other hand, would leave unfunded liabilities as of the sunset date. These liabilities would have to be reconciled with decisions on future program funding and benefit payments as well as with competing budgetary concerns generally. Adhering to the pattern of sunset dates adopted by Congress for many dedicated taxes and trust funds in recent years could require revision of the compensation program, as presently enacted.

APPENDICES

Appendix A. The Effect of Changes in Liability on Vaccine Manufacturers' Behavior

Generally, changes in the standards of product liability will affect the behavior of manufacturers and consumers in their avoidance of potential dangers in the use of a product. In certain instances it may be most efficient for manufacturers to be assigned liability for damages arising from the use of their products, while in other instances liability should rest with the consumers.

Under the present tort-law system, a manufacturer is liable for damages caused by its products if it can be shown that (1) the product was responsible for the damages and (2) the manufacturer was negligent or, in most States, the lesser standard that the product was defective. A product defect may consist of a manufacturing defect, a design defect, or the failure to provide adequate warning.

To the extent that a manufacturer is more knowledgeable than consumers of potential hazards of its products or of alternative product designs, the placement of liability on the manufacturer ensures a more efficient level of safety precautions is undertaken. In this case, the manufacturer is in a better position than consumers to evaluate the risk of possible damages caused by the product against the additional cost of further safeguards. The manufacturer should undertake all cost-effective measures to reduce possible injury. Any reduction in the liability of the manufacturer may cause it to undertake less than the optimal amount of precautions in the manufacturing and distribution of the product.[20]

On the other hand, where the safety of the product is most dependent on the manner in which the product is used by the consumer, and this use cannot be monitored at a low cost by the manufacturer, it may be most efficient to assign liability for damages to the consumer. In this case, it is the consumer who must be provided with the proper incentive to undertake precautions to the extent that they reduce the likelihood of injury.

Finally, in certain circumstances it is equally efficient to assign liability for damages to either manufacturers or consumers. This is the case where both parties are fully able to monitor each other's actions at equal cost or, alternatively, where the risk of injury from a product is not controllable by either party.

Generally, even where it is equally efficient to assign liability to either manufacturers or consumers, it is inefficient for a third party, such as the Federal Government, to bear liability for damages. If a third party bears liability, the private cost of using the product is reduced by the cost of expected damages, even though

[20] If consumers are risk-averse and manufacturers are risk-neutral, however, manufacturers may still fail to undertake an optimal level of safety precautions.

society must bear the costs of these damages. The lower private cost will increase demand for the product until the private marginal benefit of the product equals the private marginal cost. In general, this will result in excessive use of the product, because the social cost, which includes the cost of damages, exceeds the private cost.

In the case of vaccines, however, the marginal benefit to society of an individual being immunized exceeds the private marginal benefit. This is because some of the benefits of an individual's being vaccinated accrue to non-vaccinated individuals, whose chances of being infected by the disease are reduced as a greater percentage of the population becomes immunized. Thus, too few people from society's perspective will choose to be vaccinated (assuming liability for damages rests with either manufacturers or consumers). Government regulation (compulsory vaccinations) and subsidies for vaccines (or taxes for not being immunized) are methods for achieving a higher level of immunizations. Similarly, the Government's assumption of liability for possible damages may reduce the private cost of vaccines to the consumer and encourage a greater use of vaccines.

An argument is sometimes made that without a no-fault standard of liability [21] (the manufacturer is held liable for any damages without regard to fault), there will be little incentive for manufacturers to undertake research and development of safer products. This is not true if consumers can be fully informed of the safety improvements of a new product. With liability assigned to consumers (or to manufacturers only under a fault standard), manufacturers have an incentive to undertake research to develop safer products with the knowledge that consumers would be willing to pay more for the safer products. Only where consumers cannot be informed of the differences in safety between alternative products at a low cost may there be a significantly greater incentive for research to develop safer products under a standard of strict liability.[22]

A no-fault or negligence standard may also be inefficient where a manufacturer is held liable for damages caused by the use of the product, but not liable for damages that would have occurred even if the product had not been used. Consider the hypothetical case where the risk of adverse reactions to a vaccine are inversely related to successfully immunizing a vaccine-recipient.[23] Assume consumers do not know the hazards of alternative products and that vaccine manufacturers are held liable for injuries caused by the vaccine, but not for failure to prevent the disease against which the vaccine was developed. In this case, manufacturers would overprotect against possible adverse reactions caused by the vaccine and under-protect vaccine-recipients against the disease, relative to

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[21] No-fault liability would exist if, for example, the program were funded by a tax on each manufacturer equal to compensation and damages arising from use of that manufacturer's vaccine.

[22] If the returns to research accrue, in part, to parties other than those undertaking the research, as might occur in the absence of patent protection, from society's perspective there may be an underinvestment in research irrespective of the assignment of liability.

[23] This relationship is assumed only for this hypothetical example and may not be true in general.

the social optimum. This can be corrected by additionally making manufacturers liable for damages caused by the disease that could have been prevented had the vaccine been fully effective.

Under the Act, vaccine manufacturers' liability for damages in civil tort actions is changed somewhat. Vaccine manufacturers will not be held liable for damages, either directly or by subrogation, where the vaccines are properly prepared and proper warning is provided. Proper warning is assumed if the product is manufactured in compliance with certain Federal standards, unless there is evidence of fraud, intentional withholding of information relating to the safety of the vaccine, or clear and convincing evidence that the manufacturer failed to exercise due care.

The revised tort-law liability standards were believed likely to retain the proper incentives of the civil tort system that manufacturers undertake all feasible precautions in the manufacturing of vaccines and in providing warning of the possible risks of using the vaccine.[24] Where it is very difficult to detect improper vaccine preparation, however, a no-fault standard of liability on the manufacturers may be more efficient. Similarly, incentives to undertake research to develop safer vaccines may be reduced relative to a no-fault standard of liability, if it is believed that consumers cannot be easily informed of potentially safer vaccines.

[24] Whether the standards of liability provided under the tort-law changes of the vaccine injury compensation system are significantly different than under prior law is subject to interpretation. One difference with prior-law standards is that the failure to provide direct warnings to the injured party does not solely constitute improper warning.

Appendix B. Bills Introduced in the 99th Congress to Establish a National Vaccine Injury Compensation Program

H.R. 5546

H.R. 5546, introduced in the 99th Congress by Mr. Waxman and others, would have established a vaccine compensation program similar to that eventually enacted in P.L. 99-660.[25] This program was to be funded by means of a National Vaccine Injury Compensation Trust Fund, to be created in the Internal Revenue Code. Revenues from an excise tax on specified childhood vaccines (described below), and amounts recovered by the Trust Fund as a result of subrogated claims against vaccine manufacturers would have been deposited in this Trust Fund. The Trust Fund also would have had authority to borrow, as repayable advances, amounts necessary to carry out the purposes of the compensation program. (An initial advance of $40 million would have been appropriated to the Trust Fund under the bill.) Claims filed against the Trust Fund could be paid only out of the fund.

The tax under H.R. 5546 would have been imposed on the sale of a childhood vaccine by the manufacturer, producer, or importer. The amount of the tax would have been as follows: [26]

In the case of:	*Tax per dose:*
Any vaccine containing diphtheria toxoid	$0.01
Any vaccine against measles, mumps or rubella (or any combination thereof)	1.52
Any vaccine containing whole cell pertussis bacteria, extracted or partial cell bacteria, or specific pertussis antigens	1.54
Any vaccine containing polio virus (inactivated)	.01
Any vaccine containing polio virus (live)	.10
Any vaccine containing tetanus toxoid	.01

These amounts were to be adjusted for post-1986 inflation in the CPI medical care component, beginning in calendar year 1988.

H.R. 1780

H.R. 1780, introduced in the 99th Congress by Mr. Madigan and Mr. Broyhill, would have established a vaccine injury compensation program in the Department of Health and Human Services. Under this program, claims for compensation would have been de-

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[25] H.R. 5546 was reported by the House Committee on Energy and Commerce in the 99th Congress. A modified version of this bill was incorporated as title III of S. 1744 (P.L. 99-660). The tax and trust fund provisions originally included in H.R. 5546 were deleted from the legislation before it reached the House floor.

[26] These tax rates were not prepared or reviewed by the staff of the Joint Committee. Revenues from the taxes may or may not be sufficient to finance awards under the compensation program without continuing authority to borrow from general revenues.

termined by a hearing panel appointed by the Secretary of Health and Human Services. Compensation in such proceedings would have been limited to $1 million for all injuries resulting from any vaccine, with a $100,000 limit on awards for pain and suffering and emotional distress. Compensation would have been awarded on a no-fault basis.

Rather than a trust fund financed with Federal tax revenues, damages would have been paid by the respondents themselves, i.e., manufacturers and distributors of vaccine products and persons who had participated in the administration of the vaccine. A respondent would have had the option of submitting to the jurisdiction of the hearing panel, or insisting upon a civil trial under State tort law; the incentive for participating in the program would have been the liability limits above.[27] Respondents paying compensation under the program would have been permitted to bring actions against other responsible persons for all or part of the damages (e.g., a doctor held liable for administering a defective vaccine could proceed against the vaccine's manufacturer).

S. 827

S. 827, introduced in the 99th Congress by Senator Hawkins, would have established a National Vaccine Injury Compensation Trust Fund, to be funded by taxes on vaccine manufacturers and from subrogation rights. A claimant proceeding under the program would have been permanently barred from bringing a civil damage action. Liability of the trust fund would have been on a no-fault basis.

In addition to the compensation program, S. 827 would have authorized the Secretary of Health and Human Services to assist in providing insurance and reinsurance for the benefit of injured parties with respect to a specific vaccine, if the Secretary determined that adequate private insurance was unavailable. This could involve assisting in the establishment of an insurance pool among private insurance companies, or direct provision of insurance by the Federal Government. A National Childhood Vaccine Insurance Fund (distinct from the compensation program that was enacted) would have been created to pay insurance or reinsurance costs. This fund would have been financed by premiums, fees or other charges in connection with the coverage provided, and by appropriated funds.

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[27] Under H.R. 1780, a claimant could reject a decision of a hearing panel, and proceed for damages under State tort law. However, once the respondent had consented to the jurisdiction of a hearing panel, the claimant would remain subject to the statutory liability limits, even in a civil proceeding.

Appendix C. Vaccine Injury Compensation Programs in Certain Other Countries

Various foreign countries have enacted vaccine compensation systems at the national or regional level. These systems are alike, in that all provide some measure of compensation on a no-fault or reduced fault basis. The systems differ with respect to types and amounts of compensation, exclusivity of remedies, and funding sources. In several cases, these systems are part of more general programs of health and disability benefits which would result in the governments of the country underwriting the costs of vaccine injuries even without a specific vaccine compensation program.

A brief summary of three of the larger systems follows.[28]

United Kingdom

Under the Vaccine Damage Payments Act of 1979, the United Kingdom provides limited flat-rate, lump-sum compensation for vaccine injuries resulting in severe disability. This amount is considered an additional disability benefit, rather than compensation for the damage sustained. Injured persons also may seek damages in a civil action, from which the court will deduct payments received under the benefit plan. Benefits under the plan are paid from public funds.

The benefit plan applies to vaccines against diphtheria, tetanus, whooping cough, polio, measles, rubella, tuberculosis, smallpox,[29] and any other disease specified by the Secretary of State. The program is administered by the Department of Health and Social Security, under the direction of the Secretary of State.

Federal Republic of Germany

The Federal Republic of Germany provides compensation for any unusual health impairment resulting from a vaccine that is required by law, recommended by competent authority, or required for reentry into the country. Compensation includes assistance for the health and economic consequences of a vaccine-related injury, and a death benefit payable to survivors. Assistance takes the form of a pension, to be uniform with those provided under the Federal Social Assistance Act. Pensions are paid by authorities responsible for implementing the Federal pension law, as determined by the German Lander (i.e., regional) governments. The state becomes subrogated to the rights of the victim against third parties, to the extent of the assistance provided.

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[28] In addition to the countries mentioned, compensation systems are provided, *inter alia*, in France, Denmark, and Switzerland. *See*, Institute of Medicine: Division of Health Promotion and Disease Prevention, *Vaccine Supply and Innovation* (1985), Appendix E, pp. 176-182, based partly on a study conducted by Prof. Wendy K. Mariner of the Harvard School of Public Health.

[29] This vaccine was discontinued in 1971.

Japan

The Preventive Vaccination Law, as amended in 1976, provides compensation for unavoidable injuries or death occurring "through no fault of doctors or other personnel. . .". Coverage applies to all vaccines for diseases specified in the Preventive Vaccination Act and tuberculosis control law, including pertussis, diphtheria, polio, measles, rubella, tuberculosis, influenza, cholera, and smallpox.

Compensation awarded under the program includes medical expenses; disability pensions; annuities for persons caring for the disabled person; and a death benefit. No specific limits are imposed on the amount of an award. The program is funded 50 percent by the national treasury and 25 percent each by prefectures and municipalities. A recipient of compensation under the program may also pursue legal remedies.

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